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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Display Date 8.28.03  
Publication Date 8.29.03  
Certifier G. Penley

**Oral Dosage Form New Animal Drugs; Lufenuron Tablets; Milbemycin Oxime and Lufenuron Tablets; Nitenpyram Tablets**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two original new animal drug applications (NADAs) and three supplemental NADAs filed by Novartis Animal Health US, Inc. The original NADAs provide for the concurrent oral use in dogs of approved milbemycin oxime and lufenuron flavor tablets with nitenpyram tablets to kill adult fleas and prevent flea eggs from hatching and for the concurrent oral use in dogs and cats of approved lufenuron flavor tablets with nitenpyram tablets to kill adult fleas and prevent flea eggs from hatching. The supplemental NADAs provide appropriate labeling for the concurrent uses of the individual products and, for lufenuron flavor tablets, use in puppies and kittens as young as 4 weeks of age.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540; e-mail: [mberson@cvm.fda.gov](mailto:mberson@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141-204 for the concurrent

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**NADA 141-204, -205  
141-035, -175, -084**

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use in dogs of their SENTINEL (milbemycin oxime and lufenuron ) FLAVOR TABS, approved under NADA 141–084, with their CAPSTAR (nitenpyram) Tablets, approved under NADA 141–175, to kill adult fleas and prevent flea eggs from hatching. Novartis Animal Health US also filed NADA 141–205 for the concurrent use in dogs and cats of their PROGRAM (lufenuron) FLAVOR TABS, approved under NADA 141–035, with CAPSTAR Tablets to kill adult fleas and prevent flea eggs from hatching. Supplemental NADAs were also filed to NADA 141–035, NADA 141–084, and NADA 141–175 to provide appropriate labeling for the concurrent uses of these products under NADA 141–204 and NADA 141–205, and to NADA 141–035 for use of lufenuron flavor tablets in puppies and kittens as young as four weeks of age. The NADAs and supplemental NADAs are approved as of, June 11, 2003, and the regulations are amended in 21 CFR 520.1288, 520.1446, and 520.1510 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under sections 512(c)(2)(F)(ii) or (iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii) or (iii)), these NADAs and supplemental NADAs qualify for 3 years of marketing exclusivity beginning June 11, 2003.



The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801 808.

### **List of Subjects in 21 CFR Part 520**

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

### **PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. Section 520.1288 is revised to read as follows:

#### **§ 520.1288 Lufenuron tablets.**

(a) *Specifications*—(1) Tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(2) Flavored tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A) or (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(3) Flavored tablets containing 90 or 204.9 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A) or (c)(2)(ii)(B), and (c)(2)(iii) of this section.



(4) Flavored tablets containing 135 or 270 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Minimum of 10 mg lufenuron per kilogram (4.5 mg per pound (lb)) of body weight, once a month.

(ii) *Indications for use*—(A) For the prevention and control of flea populations.

(B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (c)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations*. For use in dogs and puppies 4 weeks of age and older.

(2) *Cats*—(i) *Amount*. Minimum of 30 mg lufenuron per kilogram (13.6 mg/lb) of body weight, once a month.

(ii) *Indications for use*—(A) For the control of flea populations.

(B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(3) of this section as in paragraph (c)(2)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations*. For use in cats and kittens 4 weeks of age and older.

■ 3. Section 520.1446 is amended by revising the section heading, paragraphs (a), (d)(1)(i), (d)(1)(ii), and (d)(1)(iii) to read as follows:

**§ 520.1446 Milbemycin oxime and lufenuron tablets.**

(a) *Specifications*—(1) Tablets containing: 2.3 milligrams (mg) milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.





(2) Flavored tablets containing: 2.3 mg milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

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(d) \* \* \*

(1) \* \* \*

(i) *Amount.* 0.5 mg milbemycin oxime and 10 mg lufenuron per kilogram of body weight, once a month.

(ii) *Indications for use*—(A) For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria immitis*, for prevention and control of flea populations, for control of adult *Ancylostoma caninum* (hookworm), and for removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(B) The concurrent use of flavored milbemycin oxime and lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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■ 4. Section 520.1510 is revised to read as follows:

**§ 520.1510 Nitenpyram tablets.**

(a) *Specifications.* Each tablet contains 11.4 or 57 milligrams (mg) nitenpyram.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.



(c) *Special considerations.* The concurrent use of nitenpyram tablets and flavored milbemycin/lufenuron tablets as in paragraph (d)(1)(ii)(B) of this section shall be by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) One 11.4-mg tablet for dogs weighing less than 25 pounds (lb) or one 57-mg tablet for dogs weighing more than 25 lb, as needed, for use as in paragraph (d)(1)(ii)(A) of this section.

(B) One 11.4-mg tablet for dogs weighing less than 25 lb or one 57 mg tablet for dogs weighing more than 25 lbs, once or twice weekly, for use as in paragraph (d)(1)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in § 520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in § 520.1446(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(2) *Cats*—(i) *Amount*—(A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

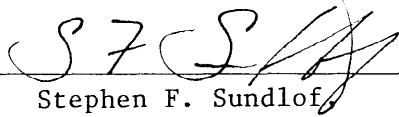
(ii) *Indications for use*—(A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.



(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

Dated: 8/18/03  
August 18, 2003.



Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

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